K080697

APR - 7 2008

510(k) Summary

AMJET Distribution, LLC
SKIN CLEAR SRVH Long Pulsed Nd:YAG Laser
510(k) Premarket Notification

Submitter:	**Global USA Distribution, LLC**
Address:	**10723 Aquila Av. S.**
Contact Person:	Ronald E. Berglund
Telephone:	952-220-3014
Facsimile:	952-888-8887
Date Prepared:	August 31, 2007
Device Trade Name:	SKIN CLEAR SRVH Long Pulsed Nd:YAG Laser
Classification Name:	Instrument, Powered, Laser 79-GEX 21 CFR 878.4810
Legally Marketed Predicate Devices:	**Sciton Profile ThermaScan (K032459), CoolTouch CT3S Nd: YAG Laser System (K043046), Cutera CoolGlide CV Laser (K023954), Cynosure Acclaim Dermatology Laser (K011828), Sciton Profile Multi-Platform System (K070388), Candela GentleYag (K033172)**

Description of the Long-Pulse Nd:YAG Laser:

The SKIN CLEAR SRVH Long Pulsed Nd:YAG Laser is a compact self-contained device that delivers a beam of laser energy at infrared wavelengths of 1064 nm and 1320 nm to the treatment site. The SKIN CLEAR SRVH Long Pulsed Nd:YAG Laser consists of six (6) primary components:

1. Laser console;
2. Internal computer;
3. Control panel and display;
4. Optical delivery system;
5. Hand set with integrated cooling (chilled sapphire optical window);
6. Foot switch

The SKIN CLEAR SRVH Long Pulsed Nd:YAG Laser is not battery operated, but is controlled and operated with the aid of computer software.

Intended Use of the Long-Pulse Nd:YAG Laser:

1064 nm: Intended for the coagulation and hemostasis of benign vascular lesions, such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lake, leg veins, spider veins and poikiloderma of civatte; and the treatment of benign cutaneous lesions such as warts, scars, striae and psoriasis. The laser is also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos, solar lentigos, Café au lait macules, seborrheic keratoses, nevi, chloasma, verrucea, skin tags, keratoses, and plaques.

The laser is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles. Additionally, the laser is indicated for the removal of unwanted hair, for the stable long-term, or permanent, hair reduction through selective targeting of merlanin in hair follicles, and for the treatment of pseudofolliculitis

	barbae. Indicated for use on all skin types (Fitzpatrick I-IV), including tanned skin. 1320 nm: For use in dermatology for incision, excision, ablation and vaporization with hemostasis of soft tissue. For use in the treatment of fine lines and wrinkles. It is also indicated for the treatment of back acne and atrophic acne scars.
Nonclinical Performance Data:	None
Clinical Performance Data:	None
Additional Information	None requested at this time
Conclusion:	The SKIN CLEAR SRVH Long Pulsed Nd:YAG Laser shares the same indications for use, similar design features (including wavelengths, laser medium, power supply, cooling and control systems), functional features (including power output, repetition rate, energy, spot sizes and energy fluence), and is therefore substantially equivalent to the above legally marketed laser systems currently in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 7 2008

Global USA Distribution, LLC
% Underwriters Laboratories, Inc.
Mr. Ned Devine
Sr. Staff Engineer
333 Pfingsten Road
Northbrook, Illinois 60062

Re: K080697
Trade/Device Name: SKIN CLEAR SRVH Long Pulsed Nd:YAG Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 31, 2008
Received: April 1, 2008

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080697

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1320 nm: For use in dermatology for incision, excision, ablation and vaporization with hemostasis of soft tissue. For use in the treatment of fine lines and wrinkles. It is also indicated for the treatment of back acne and atrophic acne scars.

Prescription Use: ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mkm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080697